



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,269	02/02/2000	Yeung Siu YU	LIFE-004	7281

7590

02/25/2003

BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD ROAD
SUITE 200
MENLO PARK, CA 94025

EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/497,269

Applicant(s)

YU ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-20 and 26-27 have been considered but are moot in view of the new ground(s) of rejection. The finality of the previous Office Action is withdrawn in view of the new grounds for rejection.

Claims 1-20, 26 and 27 are under consideration.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4, 6-8, 11-19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) in view of Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999).

Regarding Claim 1, Bamdad teaches an electrochemical test strip comprising: a reaction zone defined by opposing working and reference electrodes separated by a spacer layer (e.g. Fig. 15-17 and Column 23, line 3-Column 24, line 33) wherein at least one of the electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules (SAM) having a first sulfhydryl end group (Column 11, line 6-Column 12, line 67); and a redox reagent system in said reaction zone, said redox reagent system comprising at least one enzyme and a mediator (Column 24, line 43-Column 25, line 30 and

Art Unit: 1634

Example 17, Column 44, line 60-Column 45, line 30). Bamdad teaches the SAM comprises a functional group which adheres to the surface (e.g. sulfhydryl, Column 10, lines 30-37; Column 12, lines 3-45; and Column 15, line 37-Column 16, line 42) and a minor component for biomolecule attachment (Column 16, lines 12-15) but Bamdad does not teach the biomolecule is attached via a SAM having sulfonate end group. However, Backhaus et al teach a preferred method for modifying an electrode surface to receive a reagent comprises modifying the electrode surface with an alkyl linker group comprising a first sulfhydryl end and a second sulfonate end (Column 7, lines 45-53). Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 2, Bamdad teaches the test strip wherein the electrode comprises a metal selected from the group consisting of gold, silver and carbon (Column 12, lines 3-31) and Backhaus et al teach the similar test strip wherein the electrode comprises gold (Column 4, lines 29-48)

Regarding Claim 3, Bamdad teaches the test strip wherein the electrode comprises gold (Column 12, lines 3-31) and Backhaus et al teach the similar test strip wherein the electrode comprises gold (Column 4, lines 29-48).

Regarding Claim 4, Bamdad teaches the test strip wherein the SAM comprises the formula $\text{HS}-(\text{CH}_2)_n-\text{Y}$ wherein n is 1-6 (Column 13, lines 1-10) but they do not teach the $\text{Y} = \text{SO}_3\text{Y}$. Backhaus et al teach the similar alkyl chain terminating at one end with a sulfhydryl group which binds especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group provides a hydrophilic surface as preferred for receiving aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 6, Bamdad teaches an electrochemical test strip comprising: a reaction zone defined by opposing working and reference electrodes separated by a spacer layer (e.g. Fig. 15-17 and Column 23, line 3-Column 24, line 33) wherein at least one of the electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules (SAM) having a first sulfhydryl end group (Column 11, line 6-Column 12, line 67); and a redox reagent system in said reaction zone, said redox reagent system comprising at least one enzyme and a mediator (Column 24, line 43-Column 25, line 30 and Example 17, Column 44, line 60-Column 45, line 30). Bamdad teaches the SAM comprises a functional group which adheres to the surface (e.g. sulfhydryl, Column 10, lines 30-37; Column 12, lines 3-45; and Column 15, line 37-Column 16, line 42) wherein the SAM comprises the formula $\text{HS}-(\text{CH}_2)_n-\text{Y}$ wherein n is 1-6 (Column 13, lines 1-10) and wherein SAM comprises a minor component for biomolecule attachment (Column 16, lines 12-15) but they do not teach the $\text{Y} = \text{SO}_3\text{Y}$. However, Backhaus et al teach a preferred method for

Art Unit: 1634

modifying an electrode surface to receive a reagent comprises modifying the electrode surface with an alkyl linker group comprising a first sulfhydryl end and a second sulfonate end (Column 7, lines 45-53). Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 7, Bamdad is silent regarding the volume of the reaction zone. However, Backhaus et al teach that a sample volume between 0.1 and 10 μ l is preferred because analytical methods optimally use small sample quantities (Column 2, lines 34-38). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sample volume preferred by Backhaus et al to the reaction zone of Bamdad and to provide a reaction zone volume of between 0.1 and 10 μ l because one of ordinary skill in the art would have been motivated to minimize reaction zone volumes to thereby minimize sample volumes for the expected benefit of optimizing sample analysis as taught by Backhaus et al.

Regarding Claim 8, Bamdad teaches the test strip wherein the electrode comprises gold (Column 12, lines 3-31) and Backhaus et al teach the similar test strip wherein the electrode comprises gold (Column 4, lines 29-48).

Regarding Claim 11, Bamdad teaches the test strip wherein the SAM comprises the formula $\text{HS}-(\text{CH}_2)_n-\text{Y}$ (Column 13, lines 1-10) but they do not teach the $\text{Y} = \text{SO}_3^-$ thereby providing a salt of 2-mercaptoethane sulfonic acid as the SAM. Backhaus et al teach the similar alkyl chain terminating at one end with a sulfhydryl group which binds especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group provides a hydrophilic surface as preferred for receiving aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM (i.e. $\text{HS}-(\text{CH}_2)_n-\text{SO}_3^-$ a salt of 2-mercaptoethane sulfonic acid) thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 12, Bamdad teaches an electrochemical test strip comprising: a reaction zone defined by opposing working and reference electrodes separated by a spacer layer (e.g. Fig. 15-17 and Column 23, line 3-Column 24, line 33) wherein at least one of the electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules (SAM) having a first sulfhydryl end group (Column 11, line 6-Column 12, line 67); and a redox reagent system in said reaction zone, said redox reagent system comprising at least one enzyme and a mediator (Column 24, line 43-Column 25, line 30 and Example 17, Column 44, line 60-Column 45, line 30). Bamdad teaches the SAM comprises a functional group which adheres to the surface (e.g. sulfhydryl, Column 10, lines 30-37; Column 12, lines 3-45; and Column 15, line 37-Column 16, line 42) wherein the SAM comprises the formula $\text{HS}-(\text{CH}_2)_n-\text{Y}$ wherein n is 1-6 (Column 13, lines 1-10) wherein SAM comprises a minor component for biomolecule attachment (Column 16, lines 12-15) but they

Art Unit: 1634

do not teach the $Y = SO_3^-$ thereby providing a salt of 2-mercaptoethane sulfonic acid as the SAM. However, Backhaus et al teach a preferred method for modifying an electrode surface to receive a reagent comprises modifying the electrode surface with an alkyl linker group comprising a first sulfhydryl end and a second sulfonate end (Column 7, lines 45-53). Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving an aqueous reagents (Column 7, lines 37-40 and 45-49).). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM (i.e. $HS-(CH_2)_2-SO_3^-$ a salt of 2-mercaptoethane sulfonic acid) thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 13, Bamdad is silent regarding the volume of the reaction zone. However, Backhaus et al teach that a sample volume between 0.1 and 10 μl is preferred because analytical methods optimally uses small sample quantities (Column 2, lines 34-38). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the sample volume preferred by Backhaus et al to the reaction zone of Bamdad and to provide a reaction zone volume of between 0.1 and 10 μl because one of ordinary skill the art would have been motivated to minimize reaction zone volumes to thereby minimize sample volumes for the expected benefit of optimizing sample analysis as taught by Backhaus et al.

Regarding Claim 14, Bamdad teaches the test strip wherein the electrode comprises gold (Column 12, lines 3-31) and Backhaus et al teach the similar test strip wherein the electrode comprises gold (Column 4, lines 29-48).

Regarding Claim 15, Bamdad teaches the test strip wherein the electrode comprises palladium (Column 12, lines 3-31).

Regarding Claim 16, Bamdad teaches a method of detecting an analyte comprising apply a physiological sample to an electrochemical test strip comprising: a reaction zone defined by opposing working and reference electrodes separated by a spacer layer (e.g. Fig. 15-17 and Column 23, line 3-Column 24, line 33) wherein at least one of the electrodes has a surface modified with a homogenous surface modification layer made up of self assembling molecules (SAM) having a first sulfhydryl end group (Column 11, line 6-Column 12, line 67); and a redox reagent system in said reaction zone, said redox reagent system comprising at least one enzyme and a mediator (Column 24, line 43-Column 25, line 30 and Example 17, Column 44, line 60-Column 45, line 30). Bamdad teaches the SAM comprises a functional group which adheres to the surface (e.g. sulfhydryl, Column 10, lines 30-37; Column 12, lines 3-45; and Column 15, line 37-Column 16, line 42) and a minor component for biomolecule attachment (Column 16, lines 12-15), detecting an electrical signal in the reaction zone using metallic electrodes and measuring the detecting signal (Column 23, lines 3-60). Bamdad does not teach that the measuring determines concentration of the analyte and does not teach that the biomolecule is attached via a SAM having sulfonate end group. Backhaus et al teach a preferred method for modifying an electrode surface to receive a reagent comprises modifying the electrode surface with an alkyl linker group comprising a first sulfhydryl end and a second sulfonate end (Column 7, lines 45-53). Specifically, Backhaus et al teach that alkyl chains terminating at one end with a sulfhydryl group bind especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group to provide a hydrophilic surface as preferred for receiving a aqueous reagents (Column 7, lines 37-40 and 45-49). It would

Art Unit: 1634

have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40). Additionally, Backhaus et al teach that detection and measuring of the electrical signal determines analyte concentration (Column 5, lines 10-62) and they teach that quantitative analysis (e.g. concentration) is important and desired (Column 1, line 60-Column 2, line 10 and Fig. 4-6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the concentration determination of Backhaus et al to the signal detection of Bamdad and to determine the concentration of detected analytes based on the teaching of Backhaus et al wherein the determining analyte concentration is important and desired (Column 1, line 60-Column 2, line 10).

Regarding Claim 17, Bamdad teaches the test strip wherein the SAM comprises the formula $\text{HS}-(\text{CH}_2)_n-\text{Y}$ wherein n is 1-6 (Column 13, lines 1-10) but they do not teach the $\text{Y} = \text{SO}_3\text{Y}$. Backhaus et al teach the similar alkyl chain terminating at one end with a sulfhydryl group which binds especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group provides a hydrophilic surface as preferred for receiving aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the

Art Unit: 1634

surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 18, Bamdad teaches the test strip wherein the SAM comprises the formula $\text{HS}-(\text{CH}_2)_2-\text{Y}$ (Column 13, lines 1-10) but they do not teach the $\text{Y} = \text{SO}_3^-$ thereby providing a salt of 2-mercaptoethane sulfonic acid as the SAM. Backhaus et al teach the similar alkyl chain terminating at one end with a sulfhydryl group which binds especially well to gold electrode surfaces and when terminating at the other end with a sulfonate group provides a hydrophilic surface as preferred for receiving aqueous reagents (Column 7, lines 37-40 and 45-49). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify SAM functional groups taught by Bamdad by attaching a sulfonate group on the SAM (i.e. $\text{HS}-(\text{CH}_2)_2-\text{SO}_3^-$ a salt of 2-mercaptoethane sulfonic acid) thereby providing a hydrophilic surface for attaching and/or receiving aqueous reagents as taught by Backhaus et al (Column 7, lines 38-40). One of ordinary skill would have been motivated to apply the sulfonate group to the SAM of Bamdad to thereby increase the hydrophilic properties of the surface for the expected benefit increasing interaction with an aqueous sample e.g. body fluid samples as suggested by Backhaus (Column 7, lines 39-40).

Regarding Claim 19, Bamdad teaches the method wherein the analyte is an enzyme substrate (Column 9, lines 3-17) but they do not teach the analyte is glucose. Backhaus et al teach the similar method wherein the analyte is glucose (Example 1, Column 10, line 50-Column 11, line 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the analyte detection of Bamdad and to determine concentration of glucose as taught by Backhaus et al based on the well known importance of blood glucose determination for the obvious benefits of accurately diagnosing important physiological conditions as suggested by Bamdad (Column 9, lines 3-7).

Regarding Claim 26, Bamdad teaches the test strip of Claim 1 wherein the test strip is present in an automated instrument designed to work with test strips (Column 23, lines 20-60)

Art Unit: 1634

and Backhaus et al teach the similar test strip is present in an automated instrument which is designed to work with test strips e.g. spectrophotometer (Column 6, lines 3-23).

Regarding Claim 27, Bamdad teaches the method wherein detecting and measuring steps are preformed in an automated instrument i.e. glucose test meter (Column 23, lines 20-60) and Backhaus et al teach the similar method wherein detecting and measuring steps are preformed in an automated instrument e.g. spectrophotometer (Column 6, lines 3-23).

4. Claims 5, 9, 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bamdad (U.S. Patent No. 6,306,584, filed 10 April 1997) and Backhaus et al (U.S. Patent No. 5,869,001, issued 9 February 1999) as applied to Claims 1, 6 and 16 above and further in view of McAleer et al (U.S. Patent No. 5,708,247, issued 13 January 1998).

Regarding Claims 5, 9, 10 and 20, Bamdad teaches the test strips and methods of Claims 1, 6 and 16 comprising a redox reagent system comprising an enzyme (Column 9, lines 3-17) but they do not specifically teach the enzyme is an oxidizing enzyme. Backhaus et al teach the similar test strip and methods comprising enzymes wherein the detected analyte is glucose (Column 8, lines 16-22 and Example 1, Column 10, line 50-Column 11, line 11). Bamdad and Backhaus et al do not specifically teach the enzyme is an oxidizing enzyme e.g. glucose oxidase. However, test strips comprising glucose oxidase were well known in the art at the time the claimed invention was made as taught by McAleer et al who teach a similar test strip and method comprising a reaction zone defined by two electrodes, one of which is modified and a redox reagent system in the reaction zone comprising at least one enzyme and mediator (Abstract) wherein enzyme is a glucose oxidizing enzyme (Column 2, lines 39-43).

Art Unit: 1634

McAleer et al further teach the test strip and method comprising glucose oxidizing enzyme is important in the everyday life of diabetics because accurate monitoring of glucose can mean the difference between life and death (Column 1, lines 10-12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the glucose oxidizing enzyme of McAleer et al to the enzyme-containing test strip and method of Bamdad and Backhaus et al. Bamdad teaches their test strip and method comprising enzymes are useful for analyzing physiological interactions and medical diagnostics (Columns 9, lines 3-17 and Column 17, lines 51-67). McAleer et al teaches the importance of glucose oxidase containing test strips (Column 1, lines 10-12). Therefore, one of ordinary skill in the art would have been motivated to apply the glucose oxidase enzyme of McAleer et al to the test strip of Bamdad and Backhaus et al based on the critical importance of glucose detection for the expected benefit of accurate detection of clinically and diagnostically important glucose (McAleer et al, Column 1, lines 10-12) accurately (Bamdad, Column 1, lines 19-27 and 30-38).

Conclusion

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Application/Control Number: 09/497,269

Page 13

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
February 20, 2003